


CelgeneRiskManagement.com


Login Page



Welcome to the Celgene REMS Program

To avoid embryo-fetal exposure, Risk Evaluation and Mitigation Strategy (REMS) programs are mandatory for the Celgene products THALOMID® (thalidomide), REVLIMID® (lenalidomide) and POMALYST® (pomalidomide). The THALOMID REMS™ program (formerly known as the S.T.E.P.S.® program), REVLIMID REMS™ program (formerly known as the RevAssist® program), and POMALYST REMS™ program require prescribers and pharmacists to be certified and patients to enroll and comply with all of the requirements for each program.

If you would like to obtain more information about any of the Celgene REMS programs, please click on the program name below:



Visit www.REVLIMIDREMS.com,
to learn more about the
REVLIMID REMS™ program.



Visit www.POMALYSTREMS.com,
to learn more about the
POMALYST REMS™ program.



Visit www.THALOMIDREMS.com,
to learn more about the
THALOMID REMS™ program.

For prescribers, please enter your User Name and Password to manage your patients through a Celgene REMS program. If you do not have an online account, select Create User Account to establish an account. Patients currently enrolled in a Celgene REMS program are not required to create an online account to complete a survey. Please select Patient Surveys and enter the information requested to begin a survey.

To login to your account:

User Name

Password

[Forgot Password?](#)

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Home Page (after prescriber logon)

The screenshot shows the Celgene Home Page after a prescriber logon. The page has a dark blue header with the text "first last" on the left and "Home", "Help", and "Logout" buttons on the right. The Celgene logo is in the top left corner. The main content area is light blue and contains a central box with instructions: "Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription." Below this are three columns, each for a different product: REVIMID REMS™ (formerly known as the RevAssist® program), POMALYST REMS™, and THALOMID REMS™ (formerly known as the S.T.E.P.S.® program). Each column has a button with the product name and a link to "Prescribing Information". Below the columns is a section for the "Prescriber Dashboard" and "Manage My Account" buttons. At the bottom, there are links for "Contact Us", "Terms of Use", and "Privacy Policy", and a copyright notice for 2005-2013 Celgene Corporation.

first last

Home Help Logout

Celgene

Home

Click on a button below to access the corresponding REMS menu of operations for that product: enroll a patient, access an existing or save a new Patient-Physician Agreement Form, complete a prescriber survey or write a prescription.

For **REVIMID REMS™**
(formerly known as the RevAssist® program)

Revlimid REMS™

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **POMALYST REMS™**

Pomalyst REMS™

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

For **THALOMID REMS™**
(formerly known as the S.T.E.P.S.® program)

THALOMID REMS™

Please see full [Prescribing Information](#), including: Boxed WARNINGS, CONTRAINDICATIONS, PRECAUTIONS, and ADVERSE REACTIONS.

The Prescriber Dashboard is an optional resource that displays the status of patients under your care for a specific Celgene REMS program. A patient search function is also included to access detailed patient history information.

Select the "Manage My Account" button to view your Celgene REMS online account information.


Prescriber Dashboard **Manage My Account**


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Pomalyst REMS module


John Doe Home Help Logout


Pomalyst REMS™ POMALYST REMS™ Main Menu

 New PPAF/
Patient Enrollment


 Work with Saved/
Submitted PPAF Forms

 Prescriber Survey

 Standard
Prescription Form

 Veterans Administration
Prescription Form


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Pomalyst REMS™

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Welcome to the POMALYST REMS™ program

POMALYST® (pomalidomide), in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Important information about POMALYST and the POMALYST Risk Evaluation and Mitigation Strategy (REMS)™ program

- POMALYST is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with POMALYST provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST REMS™"
- Only prescribers and pharmacies certified by the POMALYST REMS™ program can prescribe and dispense POMALYST to patients who are enrolled and meet all the conditions of the POMALYST REMS™ program


The goals of the POMALYST risk evaluation and mitigation strategy are as follows:

1. To prevent the risk of embryo-fetal exposure to POMALYST
2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for POMALYST

For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

About the POMALYST REMS™ program

POMALYST® (pomalidomide), in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS™ program.

In order to receive POMALYST, all patients must be enrolled in POMALYST REMS™ and agree to comply with the requirements of the POMALYST REMS™ program.

Key points of the POMALYST REMS™ program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program
- The prescriber counsels patient on benefits and risks of POMALYST
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends POMALYST prescription to a certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for POMALYST REMS™ program
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
- The certified pharmacy dispenses POMALYST to patient along with a Medication Guide

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Prescriber Resources

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Enrolling in POMALYST REMS™

In order to prescribe POMALYST, you must enroll in the POMALYST REMS™ program and agree to follow the requirements of the program. You can enroll by visiting CelgeneRiskManagement.com, a website that allows prescribers to handle the REMS process for all of the Celgene REMS programs. You can also download the Prescriber Enrollment Form below and fax it to Celgene Customer Care at 1-888-432-9325.

Prescriber Enrollment Form

Prescribing POMALYST for your patients

In order to receive POMALYST, your patients must also be enrolled in the POMALYST REMS™ program. You can enroll your patients, and fill out a prescription form using CelgeneRiskManagement.com. You and your patients can also complete your mandatory confidential surveys there.

Additionally, you can also enroll your patients and write prescriptions by downloading the Desktop Software and installing it on your computer.

Enroll Your Patients at
CelgeneRiskManagement.com

Desktop Software
Installation

Installation
User Guide

Patient Prescription Form

Learning more about POMALYST REMS™

For a complete overview of the POMALYST REMS™ program, and a guide to the POMALYST REMS™ process, please see the educational materials below.

Prescriber Guide to
POMALYST REMS™ Program

POMALYST REMS™
At-A-Glance

Full Prescribing Information

Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods:

REPORTING TO CELGENE

Email:	drugsafety@celgene.com
Telephone:	1-908-673-9667
Toll-free:	1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax:	1-908-673-9115
Mail to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-FDA-1088
Fax:	1-800-FDA-0178
Mail to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787

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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436

Patient Resources

POMALYST® (pomalidomide), in combination with dexamethasone, is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

What you need to know about the POMALYST REMS™ program

Your doctor will enroll you in the POMALYST REMS™ program so that you can receive your medication. Use the materials below to learn more about the POMALYST REMS™ program, and what you need to do.

Patient Guide to POMALYST REMS™ Program 

Patient Survey Reminder Card 

Patient Medication Guide 

Visit Planned Parenthood site for Emergency Contraception Brochure

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Pharmacist Resources

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POMALYST REMS™ information for certified pharmacies

POMALYST is only dispensed from POMALYST REMS™ program certified pharmacies. To learn more about how to become a certified pharmacy please contact the Celgene Customer Care Center at 1-888-423-5436.

As a POMALYST REMS™ certified pharmacy, you must follow the requirements of the POMALYST REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

Pharmacy Guide to POMALYST REMS™ Program

Education and Counseling Checklist for Pharmacies

Full Prescribing Information

The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at CelgeneREMSPharmacyPortal.com. Contact your Celgene Account Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

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REPORTING TO CELGENE

Email:	drugsafety@celgene.com
Telephone:	1-908-673-9667
Toll-free:	1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax:	1-908-673-9115
Mall to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922

REPORTING TO THE FDA


Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-FDA-1088
Fax:	1-800-FDA-0178
Mall to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787

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